Utah Department of Health

Laboratory Bulletin

Division of Epidemiology and Laboratory Services
Bureau of Laboratory Improvement
Web page: http://health.utah.gov/els/labimp **May 2003**

Introducing

Tom Ellevold	Virology
Jessie Harbour	Virology
Don Lewis	Microbiology
Bethany Plewe	Virology

NOTEWORTHY

☞ **"NEW" PPM TEST:** The "Urinalysis-two or three glass test" was added to the PPM (provider performed microscopy) test list in 1993. BLI did not discover and add it to their list until last month. The CPT code for this test is 81020. CMS provided the following test description: "This type of specimen is used to localize pathologic sites in males. The patient voids sequentially into three bottles." Specimens are examined microscopically.

☞ **PLANNING FOR BIOLOGICAL TERRORISM:** CDC reported in its May, 2003 issue of "Emerging Infectious Diseases" on a review of outbreak investigations from 1988 to 1999. They discovered 4% of the outbreaks were caused by agents that could be used for bioterrorism. Agents included *B. anthracis, V. cholerae, Y. pestis, F. tularensis, Coxiella burnetii, Clostridium botulinum,* Venezuelan equine encephalitis virus and viral hemorrhagic fever virus. Since these agents are not commonly associated with outbreaks in the USA, CDC warns "A single case of illness or death caused by any of these organisms should suggest intentional exposure (or accidental exposure in which the perpetrators inadvertently exposed themselves to the causative agent)." CDC further requests the help of all persons investigating single disease cases or potential "outbreaks" involving these organisms to contact their local or state public health authorities. The epidemiologists should include standardized data collection in their trip reports that will aid authorities should the case signal an act of bioterrorism. Such information should include the source of the outbreak detection; date of the first case diagnosis; and the date the outbreak was recognized.

In Utah please contact:

Utah State Office of Epidemiology: (801) 538-6196
Emergencies: (888) 374-8824 (EPI UTAH)
Email = epi@utah.gov

Contents

☛ **ADULTERANTS IN URINE FOR DRUGS-OF-ABUSE TESTING:** There are hundreds of internet sites instructing persons on how to alter their urine to pass drug tests. An article by Amitava Dasgupta, Ph.D, in the February 2003 issue of MLO gave laboratories instructions on testing for the adulterants. She states:

Immediately after collection urine should be 90.5 to 98.9 degrees F
Urine specific gravity should be 1.005 to 1.030
Urine pH should be 4.0 to 10.0
Urine creatinine should be 20 to 400 mg/dL

Dr. Dasgupta gave instructions for 3 different spot tests to detect the common adulterant PCC (pyridinium chlorochromate). The easiest is to add 4 or 5 drops of 3% hydrogen peroxide to about 200 ΦL urine (6 or 7 drops from a transfer pipette). If PCC is present, the urine will turn dark brown rapidly.

Bisulfite treatment can eliminate strong nitrite adulteration interference for some drugs on certain assays. Commercial AdultaCheck strips (Chimera Research & Chemical Inc.), Mask Ultra Screen and Intect7 can detect certain adulterants.

Dr. Dasgupta feels a routine specimen integrity test including pH, creatinine, specific gravity, temperature, spot tests, and test strips can validate specimen integrity not only for screening tests but also confirmatory tests.

☛ **COAGULATION TESTING FOR PATIENTS WITH LUPUS INHIBITORS:** Anti-prothrombin antibodies interfere with warfarin in-vitro monitoring tests. Patients with lupus can develop thrombi requiring warfarin therapy. If the prothrombin time (PT) reagent used is sensitive to lupus inhibitors, the test result will be falsely high and the patient may be on too low a dosage to prevent dangerous clots.

CAP tested this interference in a recent coagulation proficiency testing event. For the specimen from a patient with a history of anti-phospholipid antibody syndrome as well as deep venous thrombosis, 31% of the participants gave therapeutic and 10% above therapeutic responses. That left 58% with the correct "below therapeutic" answer. Most, but not all prothrombin reagents are **not** affected by lupus inhibitors. Check with your manufacturer. It is doubtful waived PT methods were represented in this CAP proficiency test survey.

☛ **ROOM TEMPERATURE STORAGE AFFECTS BLOOD CELL COUNTS:** Watch out for your reference samples for CBC testing (whether you are the sender or the sendee). Dr. Gene L. Gulati reported in the January, 2003 issue of CAP Today on a study his group did for analyte stability in tubes stored at room temperature for 7 days.

WBC = stable 3 days (up to 7 if normal or above)
Platelets = stable 4 days (up to 7 if normal or above)
MCV, MPV, HCT, and RBC distribution width increased from day two onward
MCH decreased from day two onward
Other analytes were stable 7 days.

For the differential made from the stored blood, all relative percentages and absolute numbers increased over time except monocytes that decreased and basophils (author noted small number of these cells in the study) that did not change.

☛ **HIPAA RESOURCES**: There is a lot of misinformation and panic with regard to the Health Insurance Portability and Accountability Act (HIPAA). You should find answers to your questions on one of the following:

www.cms.hhs.gov/hipaa/hipaa2/default.asp
(Answers to Frequently Asked Questions)

www.cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport/default.asp
(Covered Entity Decision Tool)

askhipaa@cms.hhs.gov
(email your administrative simplification questions here) or call the HIPAA Hotline at 1-866-282-0659.

☛ **MEDICARE / MEDICAID PAYMENT BY SPECIALTY / SUBSPECIALTY:** By the end of September, 2003 the common working file (CMS computer system used to translate CLIA information to billing systems) will have the capability to reject payment for a facility not certified in the correct CLIA specialty or sub-specialty. The most common example would be a lab that does influenza testing in the winter, but failed to notify their certifying agency so the "Virology" subspecialty was not added to their certificate.

If your lab is accredited by a private agency (CAP, Joint Commission, COLA, etc.), you must notify them of all tests you perform. The agency who inspects your lab is the only one who can change your certificate. A list of the specialties / sub-specialties for which you are approved come with your CLIA certificate every two years.

This change **does not** apply to Certificate of Waiver or Provider Performed Microscopy Certificate facilities.

☛ **PROTECT B_{12} & FOLATE SAMPLES FROM LIGHT?** Frederick L. Kiechle, MD and J. Douglas Ferry, PhD stated in the March, 2003 issue of CAP today there are conflicting study results for the need to protect vitamin and folate blood samples from light. "In conclusion, B_{12} and folate specimens should be protected from light until a study using current methods demonstrates that light does not significantly alter results."

☛ **WEST NILE VIRUS IN UTAH:** Seen any mosquitoes lately? West Nile Virus infected birds are expected to make their way to Utah this year. What should you do? If you find a bird dead less than 24 hours, contact your local health department or mosquito abatement district. If you cannot reach either of them, contact the Utah State Health Department's Bureau of Epidemiology at 801-538-6191.

Don't touch the bird!

Currently the State Public Health Lab is testing human suspect menigioencephalitis cases only. An acute blood specimen must be must be collected within 10 days from symptom onset. A convalescent specimen is required. For more information check out http://health.utah.gov/wnv/.

☛ **MAILING DIAGNOSTIC SPECIMENS:** The US Postal Service (USPS) upgraded packaging requirements for mailing clinical specimens. The new regulation was effective April 30, 2003. As with IATA (airline association), the **shipper** must determine the type and danger of the specimen mailed. You have two choices.

"Diagnostic (clinical) specimen means any human or animal material, including excreta, secreta, blood and its components, tissue and tissue fluids being transported for diagnostic or investigational purposes, but excluding live animals."

Infectious substance "means a material known to contain or suspected of containing a pathogen".

Once you determine which category your shipment meets, you have to decide which of the 4 risk groups the specimen falls into. All four categories have specific packaging rules, even #1 which contains or is suspected to contain a microorganism that is unlikely to cause human or animal disease. A "diagnostic specimen" could fall into any of the four risk categories. For more detailed information try http://www.saftpak.com.

For information on shipping specimens to the Utah Public Health Lab contact Chris Peper or Wandalee Johnson at 801-584-8400.

FROM THE PATIENT'S CHART

"The patient has no previous history of suicides."

☆ Feature: ☆

TESTING FOR ANTIMICROBIAL RESISTANCE

Methicillin resistant *Staph aureus*

1. Resistance can be detected through the use of disk diffusion, screening agar, or MIC.
2. Methicillin, cloxacillin, or nafcillin disks should not be used to screen for methicillin resistance. Use a 1 Φg oxacillin disk.
3. Ampicillin disks should not be used to screen for penicillin resistance. Use a 10 unit penicillin disk.
4. Prepare the inoculum using the direct colony suspension method; **do not use the inoculum growth method.**
5. Adding 2% w/v NaCl to agar and broth dilution media is recommended for oxacillin testing.
6. Oxacillin salt-agar screening plates should be supplemented with 4% w/v NaCl and 6 Φg oxacillin /mL. Use a 1 ΦL loop to spread the inoculum in an area 10-15 mm in diameter, or use a swab to streak an entire quadrant. A positive screen will have more than 1 small colony or a light film of growth.
7. All tests must be incubated a full 24 hours (not the standard 16-18 hours) at 33-35C before reporting as susceptible. Resistance may be reported any time growth is observed after a minimum of 16 hours incubation.
8. Use transmitted light (NOT reflected light) to detect the zone of inhibition.
9. If the strain is susceptible to methicillin, but resistant to multiple other classes of antibiotics, review and/or repeat the methicillin test.
10. If the result of the disk diffusion test indicates intermediate resistance or is difficult to interpret, use the oxacillin-salt agar screening test.
11. Staph isolates that carry the mecA gene or produce PBP2a should be reported as oxacillin resistant.
12. Staph should be tested for resistance to both oxacillin and penicillin to deduce beta-lactam resistance patterns. Testing other beta-lactam antibiotics is not advised.
13. MIC breakpoints: 2 = S, 4 = R

Resistant to:	**Report as resistant to:**
oxacillin	all cephems, carbapenems, all β-lactams such as amoxicillin-clavulanic acid, piperacillin-tazobactam, ertapenem, and imipenem
penicillin (but oxacillin susceptible	penicillinase-labile penicillins (amino-, carboxy-, and ureido-penicillins)
β-lactamase (nitrocefin)	penicillinase-labile penicillins

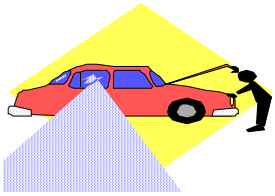
Vancomycin reduced susceptibility

1.Vancomycin testing for *Staph aureus* can be done via a vancomycin agar screening plate, an E test, or an MIC.
2. **DISK DIFFUSION DOES NOT DIFFERENTIATE SUSCEPTIBLE FROM INTERMEDIATE RESISTANCE**, even when incubated for 24 hours!
3. If the vancomycin agar screening plate is used, it must be incubated a full 24 hours at 35C, but should be confirmed by MIC.
4. QC strain ATCC 29213 must be used to ensure specificity.
5. *Staph aureus* strains with an MIC of ∃ 4 Φg/mL should be sent to a reference lab for repeat testing.
6. MIC breakpoints: #4 = S, 8-16 = I, ∃32 = R

NOTE: there is a disconnect between #5 and #6. The MIC guidelines indicate that an MIC of 4 = S, but it STILL needs to be sent to a reference lab for repeat testing.

Susan Mottice, Ph.D., Bureau of Epidemiology

Reference: NCCLS Guidelines, 2003



CLIA BITS:

ADDITIONAL WAIVED TESTS:

° Advantage Diagnostics Advantage THC and MOA

° Bio-Rad Micromat II Hemoglobin A1C Prescription Home Use

° Forefront Diagnostics Instacheck Drug Screen THC

° Applied Biotech Drugfree @Home THC and OTC

° Aerscher Hemaprompt FG for gastric occult blood

° Immunostics Immuno/Strep A Detector

° Stanbio Qustick A for Strep A

° Alatex Scientific Peace of Mind THC and OTC

° Hemosense INRATIO System for prothrombin time

° MedMira Laboratories Reveal HIV-1 rapid test in serum and plasma

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EXPIRED REAGENTS

CAP urged CMS to allow the use of expired reagents when control values were in range for the final CLIA rule. The proposal was rejected. CLIA requires a facility to adhere to the expiration date of all kit components, controls, reagents, calibrators, etc. Homemade reagents must have established outdates that are also followed.

* *

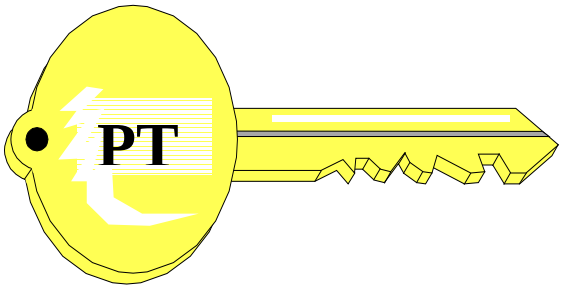
FOLLOW WAIVED TEST INSTRUCTIONS

CLIA waived tests are only "waived" if you follow the manufacturer's instructions. Check package inserts carefully for test limitations. If a whole blood glucose meter states it is used for monitoring persons with diabetes, it has not been cleared by the FDA to screen and diagnosis diabetes. If a rapid Strep kit states it is used for throat and NP swabs, it is not cleared by the FDA for use on rectal swabs.

You may use a waived test method on some other specimen type or for diagnostic purposes. Just realize the test then becomes **high complexity**. You will have to validate your use of the test as the manufacturer would to get FDA approval. Also, all testing persons would need to be qualified to perform high complexity testing.

Equals

"Half of a large intestine = 1 semicolon"



The final CLIA regulation revised the proficiency test provider grading criteria to state that 80% referee consensus was necessary to grade an analyte or testing event. The old regulation required a 90% consensus. Some providers never graded certain instrument / analyte combinations because the sensitivity was too poor to attain 90% referee consensus. Those facilities will now have a better idea of their method's comparative accuracy.

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Dr. Robert Novak from the Akron, OH Children's Hospital reviewed EXCEL throat culture proficiency test results from 1996 through 2001. He wanted to determine if participation and constant provider feedback improved a facility's ability to differentiate group A from group C Strep. He felt this differentiation has valid clinical significance in treating to prevent serious sequelae. Dr Novak found no significant change by participants during 6 years of excellent and consistent feedback by the proficiency test provider. It seems facilities fail to use proficiency test results and education information the provider gives to improve their testing quality.

For additional information email Dr. Novak at rnovak@chmca.org.

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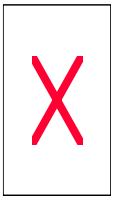
EXCEL proficiency testing scoring changes for 2003 were published in CAP Today.

"Changes to method or instrument codes cannot be made once an evaluation has been generated unless it is due to a scanning error on the part of the CAP. You must verify for accuracy information on the preprinted method page, if applicable, and entries on the result form. A result may be penalized if method information is inaccurate or missing."

"If you leave a response field blank, it may be considered an incorrect response. For example, if you normally test serum glucose and leave one of the five graded challenges blank, your score for glucose will be reduced to four out of five, or 80 percent. A penalty will not be applied to blank responses in the case of educational challenges, challenges not formally graded, or the proper use of exception codes."

"If you do not perform patient or proficiency testing for a specific analyte included in a product, it is acceptable to leave all the result fields for that analyte blank. You do not need to indicate that you do not perform this testing. This analyte is not on your testing menu that is on file with your accrediting agency, so proficiency testing results will not be expected."

Remember, CLIA regards "clerical" errors in proficiency testing the same as "clerical" errors in patient testing.



Safety Tips

SHARPS DISPOSAL FOR THE HOME USER

Medical professionals, please alert your patients who use needles, syringes or lancets at home for treating diabetes, hepatitis, multiple sclerosis, infertility, migraines or allergies to the dangers of putting their "sharps" in the regular trash. Disposing of insulin syringes in an empty bleach bottle doesn't work. The crushing action of the trash compactor breaks the bottle and the contaminated needles are loose in the trash becoming a hazard at the dumpsite.

Persons can contact their clinicians to find out whether there is a local entity (health department or hospital) willing to dispose of their sharps waste. If not, there is a Sharps Disposal By Mail System sponsored by Becton, Dickinson & Co, Waste Management, and Sharps Compliance. You obtain an approved sharps storage container. When it is full, you send it to the destruction facility and receive documentation the container was received and destroyed. This program is available to commercial as well as home settings. For information contact a BD representative or one of the 55,000 pharmacies nationwide who support the program.

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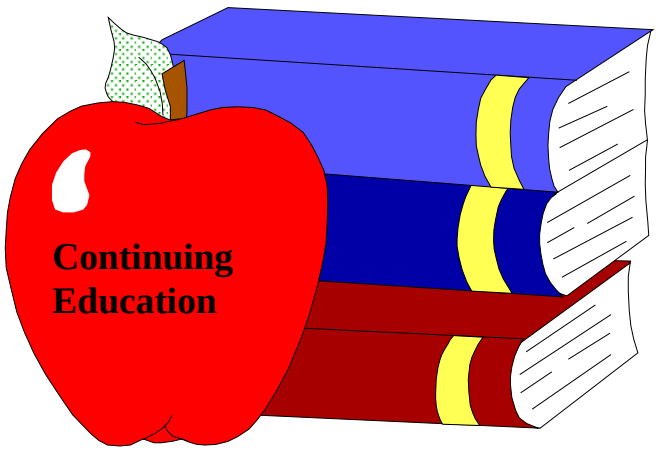
SHIPPING CONTAINER SAFETY

Fed X and Safety Pak recently reported an incident where a shipping container exploded. Dry ice was mistakenly put directly into the secondary container instead of the outer container as per instructions. The secondary container has no way to vent the dry ice. Safety Pak outer containers should have venting holes.

Since there are substantial fines for improperly packaging a biological specimen, make certain you follow the manufacturer's instructions perfectly!

Nothing is Fool-Proof to a Sufficiently Talented Fool



1. UPH Lab - BLI

Lending Library Additions:

U-83: *Packaging and Shipping for Trainers – Training Tools*, NLTN CD, March 2003

U-84: *Packaging and Shipping for Trainers – Technical Resources*, NLTN CD, March 2003

2. BIOTERRORISM BROCHURE

The Utah Department of Health has a brochure entitled "Bioterrorism Preparedness and Response – Planning Through Partnerships". The brochure (for Utah residents) covers six focus areas for preparedness and response. On the back, eight additional resources are listed (general information, disease monitoring, smallpox vaccination program, etc.). This brochure would make a great handout in lab waiting rooms, physician offices and clinics. Contact the Office of Epidemiology at 801-538-6191 for information on obtaining brochures.

3. HIPAA

HIPAA regulations require all healthcare workers who come into contact with personal health information be trained on their privacy rules by April 14, 2003. If you still need help to meet this directive, try the on-line learning system provided by the National Institute on Healthcare Regulation through Sterling Interactive at http://mailiwant.com/links.jsp?linkid=5760&subid=478032&campid=9909.

4. Lab Director Training Course

COLA is sponsoring a 20 hour CME course during the CLMA National Meeting in SLC this June. Contact COLA at www.cola.org. The link for the course is on the bottom of their home page.

1999 British GCSE exam results from 16 year olds:

Q: Give the meaning of the term "Caesarian Section".

A: The caesarian section is a district in Rome.